DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. 00N–0085]

National Environmental Policy Act; Food Contact Substance Notification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on environmental impact considerations as part of the agency's implementation of the FDA Modernization Act (FDAMA) of 1997. FDAMA amended the Federal Food, Drug, and Cosmetic Act (the act) to establish a notification process for food contact substances (FCS); this process will be the primary method for authorizing new uses of food additives that are FCS, and it will largely replace the existing food additive petition process for such substances. The regulations will expand the existing categorical exclusions to include allowing a notification submitted under the act to become effective and will amend the list of those actions that require an environmental assessment (EA) to add allowing a notification under the act to become effective in cases where a categorical exclusion doesn't apply. This will allow notifiers of FCS to claim the categorical exclusions now available to sponsors of other requests for authorization of FCS. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comment and withdraws the direct final rule.

DATES: This rule is effective [*insert date 105 days after date of publication in the* **Federal Register**]. Submit written comments by [*insert date 75 days after date of publication in the* **Federal**

Register]. If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the agency will publish a document in the **Federal Register** withdrawing this direct final rule before its effective date.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION:

I. Introduction

In 1958, Congress amended the act to require premarket approval of food additives (sections 201(s), 402(a)(2)(C), and 409 (21 U.S.C. 321(s), 342(a)(2)(C), and 348)). ''Food additive'' is defined in section 201(s) of the act as ''any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food,'' unless, among other reasons, such substance is generally recognized as safe (GRAS) by qualified experts or is prior sanctioned for its intended use. Under section 409 of the act as originally established, food additives require premarket approval by FDA and publication of a regulation authorizing their intended use. Subsequently, in 1995, FDA codified a process, the ''threshold of regulation'' process (21 CFR 170.39), by which certain food additives may be exempted from the requirement of a listing regulation if the substance is expected to migrate to food at only negligible levels (60 FR 36582, July 17, 1995).

More recently, FDAMA amended section 409 of the act to establish a premarket notification (PMN) process as the primary method for authorizing new uses of food additives that are FCS. FDA expects most new uses of FCS that previously would have been regulated by issuance of

a listing regulation in response to a food additive petition or would have been exempted from the requirement of a regulation under the threshold of regulation process will be the subject of PMN's.

As part of the agency's process of implementing FDAMA's amendments to section 409 of the act, FDA convened a public meeting on March 12, 1999, to provide interested parties with an opportunity to comment on FDA's current thinking on administration of the PMN process. As a result of the March 12, 1999, public meeting, FDA received comments on the applicability of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.* (1998)) to the notification process for food contact substances. FDA has considered those comments in developing this direct final rule and the companion proposed rule. FDA has filed copies of the transcript of the meeting and the comments received from interested parties with the Dockets Management Branch (address above) (Docket No. 99N–0235). The transcript and comments are available for public review at the Dockets Management Branch.

II. Analysis of the Applicability of NEPA to the Notification Process

As part of implementing the FDAMA amendments on food contact substances, FDA has considered the applicability of NEPA to the PMN process. As discussed in more detail in this section, FDA has concluded that agency activities under section 409(h) of the act are subject to NEPA's procedural requirements. Furthermore, as also discussed in this section, FDA currently expects that most PMN's will be subject to a categorical exclusion. (See 40 CFR 1508.4; 21 CFR 25.30 and 25.32.)

Congress enacted NEPA in 1969 to ensure that Federal Government agencies consider the environmental effects of proposed Federal actions. NEPA's purpose is to ensure that "the Agency, in reaching its decision, will have available, and will carefully consider, detailed information concerning significant environmental impacts." (*Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989).) NEPA requires agencies to "include in every recommendation or report on proposals for legislation and other major federal actions significantly affecting the quality of

the human environment, a detailed statement by the responsible official on * * * the environmental impact of the proposed action * * *. '' (See 42 U.S.C. 4332(2)(C).) Regulations implementing NEPA define ''major federal action'' as:

* * * actions with effects that may be major and which are potentially subject to Federal control and responsibility. Major reinforces but does not have a meaning independent of significantly (40 CFR 1508.27). Actions include the circumstance where the responsible officials fail to act and that failure to act is reviewable by courts or administrative tribunals under the Administrative Procedure Act or other applicable law as Agency action (40 CFR 1508.18).

FDA has concluded that under the NEPA implementing regulations, NEPA applies to FDA's decision not to object to a PMN. Under section 409(h) of the act, if FDA does not object to an FCS notification within 120 days of filing, the notification becomes effective and the substance may legally be marketed for the notified use. As discussed in more detail, under the relevant case law, FDA has concluded that this inaction constitutes final agency action under the Administrative Procedure Act (APA). As a final agency action, FDA's decision not to object is subject to NEPA's procedural requirements.

Under the APA, unless otherwise provided by statute, only ''final Agency action'' is subject to judicial review (5 U.S.C. 704). The Supreme Court recently held that to meet the finality requirement, agency action ''must mark the consummation of the Agency's decision making process—it must not be of a merely tentative or interlocutory nature,'' and ''must be one by which rights or obligations have been determined, or from which legal consequences will flow.'' (*Bennett* v. *Spear*, 520 U.S. 154, 177 (1997).) Both conditions must be satisfied for agency action to be considered ''final.'' *Id.* Inaction under section 409(h) of the act meets both parts of this test. First, the consummation requirement is met because, by operation of law, if FDA does not object, the agency can be considered to have reached its conclusion about the safety of the substance. Second, the determination of rights and obligations requirement is met because, under section 409(h)(2)(A) of the act, the notifier may now market the FCS for the notified use in the United States. This

authorization for marketing is a ''direct and appreciable'' legal consequence of the agency's decision not to object. *Id.* at 178.

FDA currently believes that a notification for a food contact substance must contain either an EA or a claim of categorical exclusion. If the environmental component of a notification is missing or deficient under 21 CFR 25.40, the agency will not accept the notification for review. In cases where the agency does not accept a notification based on deficiencies in environmental information, FDA expects to inform the notifier in writing within 30 days of receipt of the submission.

In adopting procedures to implement NEPA, Federal agencies are directed to reduce paperwork (40 CFR 1500.4 and 1500.2(b)) and to reduce delay (40 CFR 1500.5) by using several means, including the use of categorical exclusions. A categorical exclusion is a category of actions which do not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor an Environmental Impact Statement (EIS) is required (40 CFR 1508.4).

FDA has identified a number of categorical exclusions in its environmental regulations in part 25 (21 CFR part 25), including some specified uses of certain food packaging materials when approval is sought through the food additive petition process or exemption through the threshold of regulation process. For example, when the substance is a component of a coating of a finished food-packaging material or is present in such material at not greater than 5 percent-by-weight, and it is expected to remain with the finished food contact material through use by the consumer, neither an EA nor EIS is required to be submitted (§ 25.32(i)).

This direct final rule amends § 25.20(i) to add allowing a notification submitted under section 409(h) of the act to become effective to the list of those actions that require an EA. In addition this document will expand the existing categorical exclusions in § 25.32(i), (j), (k), (q), and (r) to include allowing a notification submitted under section 409(h) of the act to become effective. Any existing categorical exclusions for food additive petitions or threshold of regulation exemption requests for such food contact materials could logically be extended to cover PMN's for such

materials because the effects on the environment of allowing marketing of the substances—regardless of the process of authorization—are comparable in either case. Based on FDA's experience, the agency anticipates that a majority of PMN's will be subject to a categorical exclusion.

III. Rulemaking Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described when and how it will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as making noncontroversial amendments to an existing regulation, and FDA anticipates no significant adverse comment. Consistent with FDA's procedures on direct final rulemaking, elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule to amend the existing relevant regulations in part 25. The companion proposed rule is identical to the direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event that the direct final rule is withdrawn because of any significant adverse comment. The comment period for the direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received under the companion proposed rule will be considered as comments regarding the direct final rule.

FDA is providing a comment period on the direct final rule of 75 days after [*insert date of publication in the* **Federal Register**]. If the agency receives any significant adverse comments, FDA intends to withdraw this final rule by publication of a document in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule

will not be considered significant or adverse under this procedure. For example, a comment requesting an amendment of part 25 requirements for food additive petitions will not be considered a significant adverse comment because it is outside the scope of the direct final rule. On the other hand, a comment recommending an additional change to the rule may be considered a significant adverse comment if the comment explains why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

If FDA withdraws the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule under the usual notice-and-comment procedures of the APA (5 U.S.C. 552 *et seq.*). If FDA receives no significant adverse comment during the specified comment period, FDA intends to publish a confirmation document in the **Federal Register** within 30 days after the comment period ends. Because the direct final rule grants an exemption from the requirement to file an EA, under 5 U.S.C. 553(d), the rule may be made immediately effective. Therefore, FDA intends to make the direct final rule effective on the date the confirmation document is published in the **Federal Register**.

IV. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA has examined the economic implications of this final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way,

adversely affecting competition, or adversely affecting jobs. A regulation is also considered significant if it raises novel legal or policy issues. FDA has determined that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4), requiring cost-benefit and other analyses, in section 1531(a) defines a significant rule as "a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year." FDA has determined that this final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, FDA has determined that this final rule is not a major rule for the purpose of congressional review.

The final rule allows firms using the new notification process for food contact substances to claim the same categorical exclusions from the requirement of an EA that are currently applicable for food additive petitions and threshold of regulation exemption requests for the same uses. The rule therefore imposes no additional costs on producers or consumers.

B. Small Entity Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect on the rule on small entities. The agency certifies that this final rule will not have a significant impact on a substantial number of small entities.

This final rule will permit notifiers under the new notification process for FCS to claim the same categorical exclusions from the requirement of an EA that are currently applicable for food additive petitions and threshold of regulation exemption requests for the same uses. The final rule will not result in any additional costs to any firm. Therefore, this final rule will not have a significant impact on a substantial number of small entities.

V. Paperwork Reduction Act of 1995

This direct final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Comments

Interested persons may, on or before [*insert date 75 days after date of publication in the* **Federal Register**], submit to the Dockets Management Branch (address above) written comments regarding this direct final rule. This comment period runs concurrently with the comment period for the companion proposed rule. Two copies of any comment are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered comments regarding the proposed rule and this direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the companion proposed rule and the direct final rule will be considered comments on the proposed rule.

VIII. Report to Congress

For purposes of congressional review requirements under 5 U.S.C. 801–808, the report to Congress for this direct final rule will be issued when FDA confirms the effective date of this rule. Thus, no report is due at this time. If, however, a significant adverse comment is received, the agency will withdraw this direct final rule and no report will be issued to Congress.

List of Subjects in 21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 25 is amended as follows:

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

1. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

2. Section 25.20 is amended by revising paragraph (i) to read as follows:

§ 25.20 Actions requiring preparation of an environmental assessment.

* * * * *

(i) Approval of food additive petitions and color additive petitions, approval of requests for exemptions for investigational use of food additives, the granting of requests for exemption from regulation as a food additive under § 170.39 of this chapter, and allowing notifications submitted

under 21 U.S.C. 348(h) to become effective, unless categorically excluded in § 25.32(b), (c), (i), (j), (k), (l), (o), (q), or (r).

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3. Section 25.32 is amended by revising paragraphs (i), (j), (k), (q), and (r) to read as follows:

§ 25.32 Foods, food additives, and color additives.

* * * * *

(i) Approval of a food additive petition or GRAS affirmation petition, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, when the substance is present in finished food-packaging material at not greater than 5 percent-by-weight and is expected to remain with finished food-packaging material through use by consumers or when the substance is a component of a coating of a finished food-packaging material.

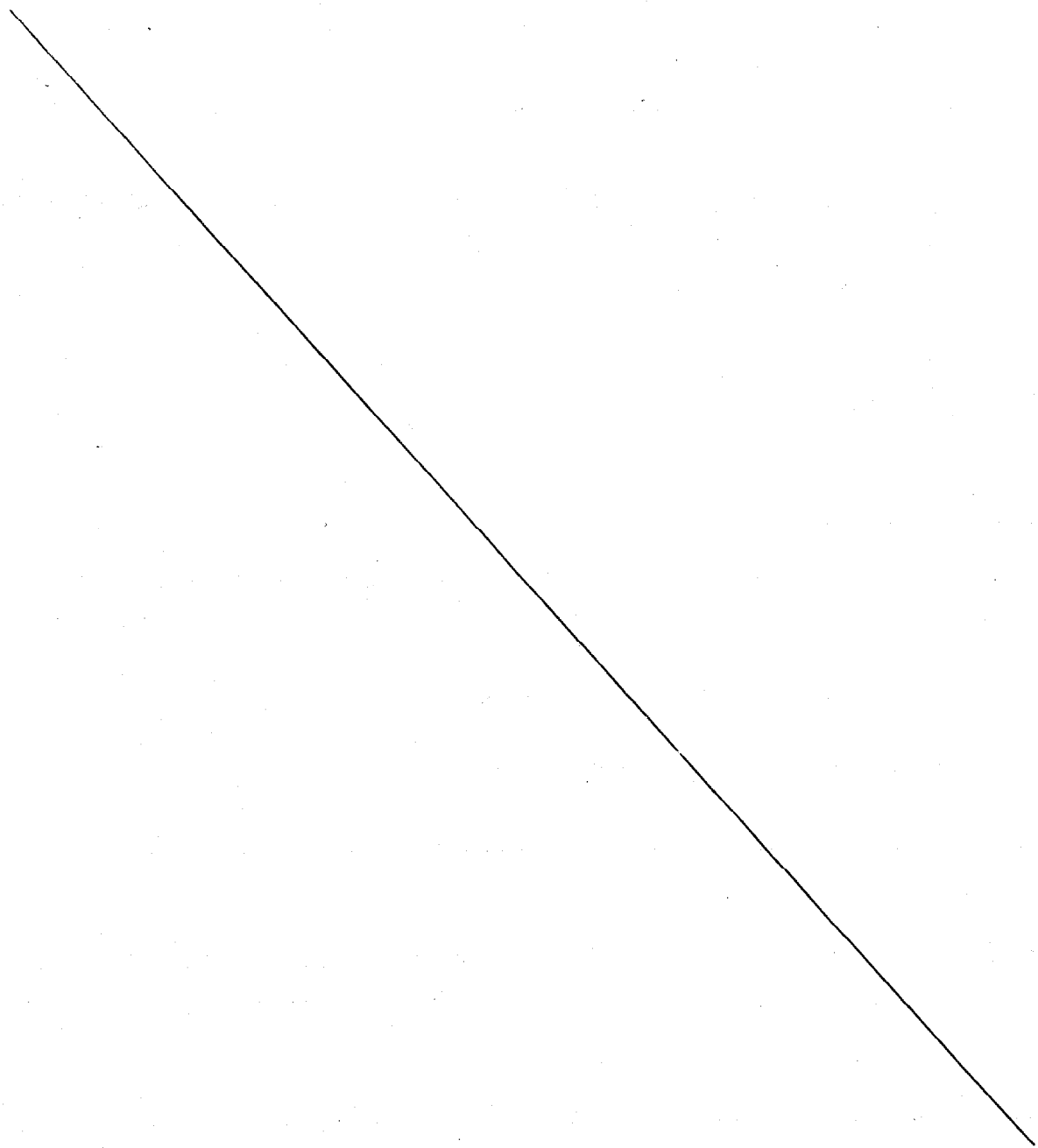
(j) Approval of a food additive petition or GRAS affirmation petition, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, when the substance is to be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use.

(k) Approval of a food additive petition, color additive petition, or GRAS affirmation petition, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food.

* * * * *

(q) Approval of a food additive petition, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance registered by the Environmental

Protection Agency under FIFRA for the same use requested in the petition, request for exemption, or notification.



(r) Approval of a food additive petition, color additive, GRAS affirmation petition, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance that occurs naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

Dated: 1/24/00
January 24, 2000

Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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